K090692

MAY - 8 2009

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the ORTHOLOC® 2.0 / 2.4 System.

Submitted By:	Wright Medical Technology, Inc.
Date:	March 13, 2009
Contact Person:	Fred W. Bowman, P.E. Senior Regulatory Affairs Specialist
Proprietary Name:	**ORTHOLOC® 2.0/2.4 Plate & ORTHOLOC® 2.0/2.4 Screw**
Common Name:	Bone Fixation Plate & Bone Screw
Classification Name and Reference:	21 CFR 888.3030 Plate, Fixation, Bone – Class II 21 CFR 888.3040 Screw, Fixation, Bone – Class II
Device Product Code and Panel Code:	Orthopedics/87/HRS Orthopedics/87/HWC

DEVICE INFORMATION

A. INTENDED USE

The ORTHOLOC® 2.0 / 2.4 Plate System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients. Examples include:

Metatarsal or metacarpal fractures and osteotomies
Phalanges fractures and osteotomies

B. DEVICE DESCRIPTION

The design features of the ORTHOLOC® 2.0 / 2.4 System are described below.

- Consists of a variety of flat and pre-contoured plate geometries
- Plates feature compression slots and locking screw holes
- Manufactured from Titanium and Titanium Alloy
- Screws are available in both locking and non-locking designs
- Screws are available in 2 diameters and 7 lengths in the small diameter and 12 lengths in the large diameter

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C. SUBSTANTIAL EQUIVALENCE INFORMATION

The design features, material, and indications for use of the ORTHOLOC® 2.0/2.4 System are substantially equivalent to previously cleared predicate devices. The safety and effectiveness of the ORTHOLOC® 2.0/2.4 System is adequately supported by the substantial equivalence information, materials information, and analysis data provided within this Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY - 8 2009

Wright Medical Technology, Inc.
% Mr. Fred W. Bowman, P.E.
Senior Regulatory Affairs Specialist
5677 Airline Road
Arlington, Tennessee 38002

Re: K090692
Trade/Device Name: Ortholoc 2.0/2.4 Plate & Ortholoc 2.0/2.4 Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS, HWC
Dated: March 13, 2009
Received: March 16, 2009

Dear Mr. Bowman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for David Krause

Mark N. Melkerson
Director
Division of Surgical, Orthopedic,
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K090692

Indications for Use

510(k) Number (if known):

Device Name: ORTHOLOC® 2.0 / 2.4 Plate System

Indications For Use:

The ORTHOLOC® 2.0 / 2.4 Plate System is intended for use in stabilization of fresh fractures, revision procedures, joint fusion and reconstruction of small bones of the hand, feet, wrist, ankles, fingers and toes. The system can be used in both adult and pediatric patients. Examples include:

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Phalanges fractures and osteotomies

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K090692